

REMARKS

This Amendment is submitted in response to the Office Action dated October 3, 2003 and the Office Communication mailed April 6, 2004, which indicated that the previously submitted Response Under 37 C.F.R. § 1.116 (filed December 3, 2003) was considered not fully responsive and, thus, did not qualify as a RCE submission under 37 C.F.R. § 1.114, and the Office Communication mailed April 20, 2004, which provided a new shortened statutory period of one month or thirty days to complete the reply, thus indicating that the previously submitted Response Under 37 C.F.R. § 1.116 was considered a *bona fide* attempt to provide a complete reply and, thus, tolled the period for reply. Accordingly, the new due date for response is May 20, 2004.

Reconsideration of the above-identified application in view of the present amendment and the following remarks is respectfully requested. Prior to the present amendment, claims 9-11, 13-16, and 27 were pending and under consideration. By the present amendment, these claims are canceled, and new claims 34-40 are added, which correspond to previously elected claims 17-19, 22-24, 27 and 28. Claims 34 and 40 include slight amendments as compared to the originally elected claims, in order to more specifically describe certain aspects of the presently claimed invention. Support for these amendments may be found throughout the specification and claims as originally filed and, accordingly, does not constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 12, 17, 20, and 27 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. More specifically, claim 12 allegedly lacks antecedent support in reciting "the total cell count." In addition, claim 17 is allegedly unclear in its recitation of "a value," lacks antecedent support in reciting "the detected viable cell value,"

and is confusing regarding its correlation step. Claims 20 and 27 allegedly lack antecedent support in reciting "the total cell count" and "the method," respectively. Also, claim 27 is allegedly indefinite in reciting "or other methods of counting," and confusing regarding the correlation of the instructions with means for determining cell counts.

Applicants traverse this basis of rejection and submit that the skilled artisan would clearly understand the metes and bounds of the claimed subject matter, particularly in light of the teachings of the instant specification. Nonetheless, without acquiescence to this basis of rejection, claims 12 and 20 have been canceled, and claim 41, which corresponds to previous claim 27, does not recite "the total cell count" or "other methods of counting viable cells." Applicants further submit that the skilled artisan would understand the metes and bounds of claim 34, which corresponds to previous claim 17 but has been comparatively amended to clearly indicate that the claimed method involves detecting the amount of enzymatically altered molecule or dye. In light of these amendments and remarks, Applicants respectfully request that these bases of rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 9-12, 14, 15, 17-20, 22, and 23 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Breeuwer *et al.* Specifically, the Examiner alleges that Breeuwer *et al.* teaches a method for detecting cell viability by flow cytometry using fluorescein diacetate dye, which diffuses into or is translocated into cells, where it is detectably altered by esterase activity in viable cells.

Claims 9, 11, 12, 14, 16, 17, 19, 20, 22, 24, 27, and 28 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Sarkadi *et al.* The Examiner alleges that Sarkadi *et al.* disclose a method and kit for detecting viability of cells using a fluorometer and calcein AM dye, which is converted from a non-fluorescent form to a fluorescent form in viable cells.

Applicants respectfully traverse these bases of rejection and submit that neither reference anticipates the invention, since neither reference teaches each element of the instant claims. Without acquiescence to these bases of rejection and solely for the purposes of expediting prosecution of the instant application, claims 9-12, 14-20, 22-24, 27 and 28 have been

canceled. Applicants submit that new claims 34 and 40, corresponding to previous claims 17 and 27, and new claims 35-39 dependent therefrom, are clearly novel in light of Breeuwer *et al.* and Sarkadi *et al.*

Applicants submit that Breeuwer *et al.* fails to anticipate the presently claimed invention, since it fails to describe a method of quantitating viable cells that involves correlating a measurement of enzymatic activity of a cell population with a standard value in order to quantitate viable cells in a sample, as recited in instant claim 34. To the contrary, Breeuwer *et al.* teaches that viable cells extrude the enzymatically altered fluorescent molecule, carboxyfluorescein, and that viable cells, therefore, do not produce measurable fluorescence activity (*see, e.g.*, Fig. 9).

Applicants further submit that Sarkadi *et al.* fails to anticipate the presently claimed invention, since it also fails to teach the step of correlating a measurement of total enzymatic activity of a cell population with a standard value in order to quantitate viable cells in a sample, as recited in instant claim 34. Rather, Sarkadi *et al.* teaches a method that requires determining the accumulation rate of fluorescence accumulation over time. Thus, the method described by Sarkadi *et al.* does not include correlating a total amount of enzymatically altered compound or dye to a standard value. In addition, Sarkadi *et al.* do not teach a method of quantitating viable cells. Sarkadi *et al.* is directed to a method of examining the effect of inhibitors of transport proteins on the accumulation rate of a fluorescent compound in a cell, in order to identify modulators of multi-drug resistance. The method of Sarkadi *et al.* is clearly not directed to viable cells in a population, as recited in claim 34.

Furthermore, Applicants submit that neither Breeuwer *et al.* nor Sarkadi *et al.* teach a kit as recited in claim 40, which comprises a cell suspension solution, a cell penetrating dye, and instructions.

In light of these remarks, Applicants respectfully request that these bases of rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 13 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Breeuwer *et al.* or Sarkadi *et al.* in view of Katz. More specifically, the Examiner concedes that neither Breeuwer *et al.* nor Sarkadi *et al.* teach using UV absorption to determine total cell count. However, the Examiner alleges that Katz discloses a method of detecting both viable and nonviable cells by contacting cells with a fluorescent dye, counting dead cells that fluoresce using a microscope, killing all cells using heat, and then determining the total count of cells by ultraviolet absorption. The Examiner alleges that it would have been obvious to incorporate the teachings of Katz related to determining counts of both viable and total cells using UV absorption measurements into a method of determining the amount of viable cells as taught by Breeuwer *et al.* or Sarkadi *et al.*

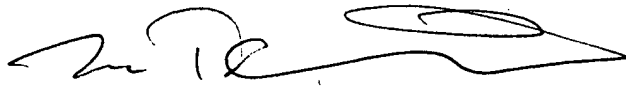
Applicants respectfully traverse this basis of rejection and submit that neither combination of references teaches each element of the claimed invention and, therefore, both combinations of references fail to establish a *prima facie* case of obviousness of the claimed invention. However, to expedite prosecution of the instant application and without acquiescence to this basis of rejection, claims 13 and 21 has been canceled. Accordingly, Applicants respectfully request that this basis of rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants submit that the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. While every effort has been made to place this application in condition for allowance, should any remaining issues exist, the Examiner is requested to contact the undersigned attorney at (206) 622-4900.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:jto
Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

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